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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/763,831 | 07/11/2001 | Chih-Ming Chen | 141-201 | 3745 |

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|---|---|
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| ART UNIT | PAPER NUMBER |
|---|---|
| 1615 | |

DATE MAILED: 09/24/2002 6

Please find below and/or attached an Office communication concerning this application or proceeding.

| Offic Action Summary | Applicati n No. 09/763,831 | Applicant(s) CHEN ET AL. | |
|---|---|---|---|
| | Examin r Susan Tran | Art Unit 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period f r Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disp sition of Claims**

4)☒ Claim(s) 1-11 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-11 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

Receipt is acknowledged of applicant's Request for Extension of Time and Declaration filed 07/11/01.

### *Specification*

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-5, 8, and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 3 are indefinite for failing to further limit the subject matter of claim 1. Claim 1 recites the transitional phrase "consisting essentially of" which excludes the use of other ingredients, as well as ingredients recite in claims 2 and 3. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form.

Claims 2 and 3 recite the limitation "acid resistant component" in line 2. There is insufficient antecedent basis for this limitation in the claims. The limitation "acid resistant" has not been recited in claim 1. Further clarification is requested.

Claim 8 recites the limitation "sodium lauryl sulfate as the surface active agent" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not recite "surface active agent". Further clarification is requested.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,174,548 ('548). Although the conflicting claims are not identical, they are not patentably distinct from each other because USPN '548 in claim 1 claims a stable pharmaceutical composition consisting essentially of omeprazole core and an enteric coating layer without a separating layer (sub-coating layer). Lysine and arginine as an alkaline material are found in claims 1 and 2. Surface active agent is found in claim 4. Enteric coating agent is found in claim 3. Therefore, the skilled artisan would expect a similar stable pharmaceutical composition from the use of the instant invention give the claims

of '548. There are no unusual and/or unexpected results, which would rebut prima facie obviousness.

### *Claim Rejections - 35 USC § 102*

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-11 are rejected under 35 U.S.C. 102(a/e) as being anticipated by Chen et al. US 6,174,548.

Chen teaches pharmaceutical composition consisting essentially of a core, including omeprazole, surface active agent, filler, alkaline agent, and binder; a single enteric coating layer on said core (see abstract). The enteric coating comprises hydroxypropylmethyl cellulose phthalate, and further including inert processing aid, *e.g.*, talc (column 2). The alkaline agent is lysine or arginine, the surface active agent is sodium lauryl sulfate (columns 2-3, and examples). The enteric coating agents are mixed in organic solvent, *e.g.*, isopropyl alcohol (examples).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al.

Chen is relied upon for the reason stated above. Chen teaches all the claimed ingredients as well as the claimed dosage form, it would have been *prima facie* obvious for one of ordinary skill in the art to, by routine experimentation obtain the claimed invention because Chen also recognizes the properties desired by the applicant, *e.g.*, a stable dosage formulation of omeprazole without the need of an intermediate coating layer, which is stable upon prolonged storage, stable when administered, and is capable of providing the desired therapeutic effect.

Claims 1-7, and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Odidi et al. US 6,296,876, in view of Kim KR 9208161B (abstract only).

Odidi teaches pharmaceutical formulation comprising core, at least one sub-coating layer, and an enteric coating layer (column 2). The core comprising omeprazole mixed with disintegrants, stabilizers, fillers, acid sequestering substance, and excipients (column 3, lines 23-52). Enteric coating containing hydroxypropylmethyl cellulose phthalate and talc (column 4, lines 30-35, and examples). Odidi does not specifically

teach arginine or lysine as stabilizers, fillers, acid sequestering substance, or excipients in the core.

Kim teaches oral dosage form comprising core including, omeprazole mixed with stabilizing agent, such as lysine or histidine (abstract). Thus, it would have been *prima facie* obvious for one of ordinary skill in the art to modify the pharmaceutical formulation of Kim using lysine as a stabilizing agent in view of the teaching of Kim because the references teach the advantageous results in the use of oral dosage form of omeprazole. The unexpected result would be an omeprazole oral dosage form having excellent resistance to dissolution in acid media, and having good stability during long-term storage.

It is noted that the cited references containing a sub-coating layer. However, absent showing criticality, the absent of a sub-coating layer does not impart patentably distinct (see *In re* Larson, 340 F.2d 965, 144 USPQ 347 (CCPA 1965) (Omission of additional framework and axle which served to increase the cargo carrying capacity of prior art mobile fluid carrying unit would have been obvious if this feature was not desired.); and In re Kuhle, 526 F.2d 553, 188 USPQ 7 (CCPA 1975) (deleting a prior art switch member and thereby eliminating its function was an obvious expedient). Furthermore, the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps, and those that *do not materially affect the basic and novel* characteristic of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461. For search and examination purposes, absent a clear indication in the specification of what the basic and novel characteristics actually are, "consisting

essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ at 1355 ("PPG could have defined the scope of the phrase consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). ***When an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention.*** In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989).

### *Pertinent Arts*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lovgren et al., Kim, Klokkers et al., and Depui et al. are cited as being of interest for the teaching of oral dosage form of omeprazole.

### *Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
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